

Application No. 10/535,723
Amdt. dated September 25, 2006
Response to the Office Action of May 25, 2006

REMARKS/ARGUMENT

This response is submitted under 37 C.F.R. § 1.111 to the Office Action of May 25, 2006.

Claims 2 through 13 are pending in the application with claims 2-12 having been currently amended, claim 1 canceled, and new claim 13 added. Support for new claim 13 appears in the specification as filed in the paragraph bridging pages 1 and 2.

No additional fee is believed to be due.

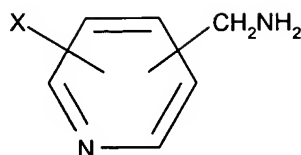
Claim 1 has been objected to because it did not have a period at the end of the claim.

Claim 1 has been canceled.

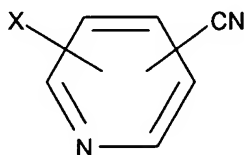
Claims 1-12 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the structure of compound I as set forth in the Preliminary Amendment filed on or about May 20, 2005, was incorrect in that a methylene group situated between the primary amine group and the 1-position of the pyridine ring was inadvertently omitted. In new claim 13, upon which all the claims remaining in the application are directly or indirectly dependent, the error has been corrected. Accordingly, it is requested that the rejection of claims 1-12 under 35 U.S.C. 112, first paragraph, be withdrawn.

Claims 1, 2, 8, 9, and 10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-101646.

JP 10-101646 is directed to the problem of obtaining a compound of the structure



useful as an important intermediate for medicines, etc., in high yield with the suppression of by-product formation, by using a manganese-containing Raney catalyst in reducing a cyanopyridine compound with hydrogen in the presence of ammonia. According to the patent, the problem is solved by reducing a cyanopyridine compound of the formula



(X is hydrogen or a halogen) with hydrogen gas usually in the presence of 5-60 weight percent of NH_3 by using generally ≥ 1 weight percent of a manganese-containing Raney catalyst to produce the above aminomethylpyridine. In the reaction, preferably a solvent such as methanol of 1-15 times as much as the cyanopyridine compound is used, the Mn content of the Raney catalyst is 2-50 weight percent and the amount of the Raney catalyst used is 3-50 weight percent. The reaction temperature is 0-200°C, preferably 20-100°C, the reaction pressure is common, to

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be concrete, 0-50kg/cm² G, preferably 1-30kg/cm² G. After the reaction, the catalyst is separated and the compound of formula II is recovered by distillation.

Claims 1, 2, 3, and 4 have been rejected under 35 U.S.C. 102(a) as being anticipated by Dann et al. (WO 02/16322).

Claims 8 and 9 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Dann et al., *supra*.

WO 02/16322 to Dann et al. discloses a process for the preparation of 2-aminomethylpyridine derivatives falling within the definition of the compound of formula (I) according to the present invention, by catalytic hydrogenation of 2-cyanopyridine derivatives falling within the definition of the compound of formula (II) according to the present invention. Nevertheless, the process disclosed in Dann et al. is a catalytic hydrogenation conducted in the presence of a catalyst chosen from a list of possible catalysts in which Raney nickel is not cited (*see* page 4, lines 1-2: Raney nickel is not cited). Furthermore, the use of acetic acid to perform the catalytic hydrogenation is not disclosed in Dann et al. (*see* page 4, lines 13-21: acetic acid is not cited).

Thus, even if Dann et al. disclose a process for preparing compounds similar to compounds of formula (I) according to the present invention by catalytic hydrogenation of similar starting material, the experimental conditions of these processes are totally different (catalyst, solvent, etc.).

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Based on the above elements, novelty of process covered by pending claim 13 (and therefore dependent claims 2 to 12) in view of Dann et al. should therefore be acknowledged by the Examiner.

As mentioned above, Dann et al. disclose a process for the preparation of 2-aminomethylpyridine derivatives falling within the definition of the compound of formula (I) according to the present invention, by catalytic hydrogenation of 2-cyanopyridine derivatives falling within the definition of the compound of formula (II) according to the present invention using a catalyst chosen as being palladium, platinum, ruthenium, nickel or cobalt (preferably palladium), in the presence of an alcohol solvent, at a temperature of from 0°C to 60°C (preferably of from 20°C to 30°C), under a hydrogen pressure of from 1 to 4 bar.

The teaching of Dann et al. is clearly focused on the use of a palladium catalyst to prepare the compound of formula (I) starting from the compound of formula (II) (*see* page 4, lines 5-6 & Example 1, page 10). Palladium catalysts are well known by the ordinarily skilled artisan as facilitating by-product dehalogenation reactions. Furthermore, the teaching of Dann et al. clearly and strongly recommends the use of a catalyst inhibitor to improve selectivity of the reaction by limiting these dehalogenation by-product reactions (*see* page 4, line 29, to page 5, line 10). Thus, nothing in the teaching of Dann et al. discloses or even suggests the use of Raney nickel in acetic acid to prepare 2-aminomethylpyridine substituted by a halogen atom by catalytic hydrogenation of 2-cyanopyridine substituted by a halogen atom in acceptable yields at

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an industrial scale and avoiding the use of catalyst inhibitors which are expensive and difficult to be used in an industrial process to prevent by-product dehalogenation reactions.

JP 10-101646 makes no mention or suggestion of the existence of such a technical problem (compounds cited in this document are not always substituted by a halogen atom) nor of the possible use of Raney nickel in acetic acid.

Thus, based on the above elements, it is submitted that neither JP 10-101646 nor WO 02/16322 to Dann et al., alone or in combination, renders obvious the invention covered by pending claim 13 (and, consequently, of dependent claims 2 to 12).

Thus, it is requested that the rejections of:

claims 1, 2, 8, 9, and 10 under 35 U.S.C. 103(a) as being unpatentable over JP 10-101646;

claims 1, 2, 3, and 4 under 35 U.S.C. 102(a) as being anticipated by Dann et al. (WO 02/16322); and

claims 8 and 9 under 35 U.S.C. 103(a) as being unpatentable over Dann et al., *supra*; be withdrawn.

Claims 11 and 12 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as their invention. Specifically, according to the Examiner:

Claims 11-12 contain the trademark/tradename Raney nickel. Where a trademark or trade name is used in a claim as a limitation to identify or describe particular

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material or product, the claim does not comply with the requirements of 35 U.S.

C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App.

1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify the source of goods, and not the goods themselves. Thus a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a nickel catalyst, however, it is not clear which nickel catalyst is described, since 'Raney Nickel' can describe several nickel catalysts, and accordingly, the identification/description is indefinite.

This rejection is respectfully traversed.

First, "Raney nickel" is not a registered trademark. Applicants acknowledge that "Raney" is a registered trademark, owned by W. R. Grace & Co. Corporation, for "catalyst in powder, ingot or lump form, comprising either hydrogenating catalysts being special forms of nickel, copper, cobalt, iron or other metal, or an alloy of aluminum with nickel, copper, cobalt, iron or other metals."

It is the Applicants' position that "Raney nickel" designates a solid catalyst composed of fine grains of a nickel aluminum alloy used in many industrial processes and very well-known by the skilled artisan. Definitions of such a catalyst can easily be found in any encyclopedia, chemistry books, or even on the Internet.

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As a specific example, Applicants' representative went online into the *USPTO Patent Full-Text and Image Database* and searched for "Raney" in the specifications of issued U.S. patents, resulting in 15,875 hits. He then searched for "Raney nickel" in specifications and got 14,405 hits. Finally, he searched the *issued claims* for the term "Raney nickel" and got 779 hits. Clearly, this term is very well-known in the art and is one that the Patent Office has permitted in issued patent claims many, many times. It is submitted that in view of this record, it would be highly discriminatory against the present Applicants if they were to be denied a patent on the grounds that "Raney nickel" is indefinite. Accordingly, it is requested that the rejection of Claims 11 and 12 under 35 U.S.C. 112, second paragraph, be withdrawn.

In view of the foregoing, it is submitted that this application is now in condition for allowance, and an early Office Action to that end is earnestly solicited.

Respectfully submitted,



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